

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	Application No. 10/533,928	Applicant(s) BERTHON-JONES ET AL.	
	Examiner CLINTON OSTRUP	Art Unit 3771	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 February 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 19-44.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
 13. ☒ Other: Attached PTO-892 Notice of References Cited.

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771

/Clinton Ostrup/
Examiner, Art Unit 3771

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments have not been found convincing. Regarding claim 19, Applicant argues on page 12, second paragraph, that Amarasinghe does not disclose at least one selected frame portion engaged with the cushion so that the cushion is adjustable in accordance with a position of the at least one selected frame portion relative to the main body of the frame.

However, the examiner respectfully disagrees. The selected frame portion (brace) 12 of Amarasinghe is engaged with the cushion (16) via the main body (13) and by wrapping around the cushion as seen in figure 2. Moreover, Amarasinghe discloses on page 8, lines 8-16 that "It is also intended that the brace could be configured so as to engage brace receiving features that may be provided by a mask cushion clip. In this way the brace may be accurately positioned relative to the mask frame while serving to secure the cushion clip and cushion to the mask frame." Thus, it is clear that Amarasinghe discloses at least one selected frame portion (12) engaged with the cushion (16) via the main body or a cushion clip.

Regarding the claimed limitation that the cushion is adjustable (capable of being adjusted) in accordance with a position of the at least one selected frame portion relative to the main body of the frame; it is the examiner's position that the cushion (which is attached to and forms the shape of a users face in figure 12) is adjustable (capable of being adjusted) by taking the straps on and off the patient; particularly given the malleability of the brace and the brace being detachably connected to the mask.

Regarding Applicant's argument on page 13, last paragraph, that frame portion is engaged with the cushion and not the other features identified by the examiner, applicant is reminded that the claims are given their broadest reasonable interpretation. Since applicant has not provided any specific definition for term "engaged"; the term engaged has been given its common dictionary meaning "attached to."

Regarding claim 20, and applicant's argument, on page 14, fourth full paragraph, that Amarasinghe does not disclose a portion of the brace that is adjusted relative to the mask shell when the mask assembly is located on the user; the examiner respectfully disagrees. Amarasinghe discloses, that "Because of the versatility offered by the brace of the present invention, it also offers the possibility for incorporating a mask stabilizing feature independent of or in addition to the inclusion of the headgear attachment points. An example of such a stabilizing feature is illustrated in the accompanying drawings in the form of a forehead stabilizing section 20 [a part of the brace 12]. The stabilizing portion 20 takes the form of a portion of the brace extending clear of the mask shell so as to provide an elevated engagement point and/or to contact a portion of the user's face, in this case the forehead. The malleability of the wire used to form the brace allows the position of the stabilizing portion to be adjusted for individual patients. In FIG. 2 it can be seen that the forehead stabilizing portion 20 is in near contact or contact with the user's forehead thereby limiting movement of the accompanying mask frame and mask cushion towards to the user's face in the region of the nasal bridge. This stabilizing feature is achieved due to the relatively rigid engagement of the brace in relation to the mask shell.

Regarding claim 22, applicant's arguments on page 15, third paragraph, that Amarasinghe does not disclose or suggest that the brace head strap attachment points 15 wraps around the cushion when the straps are fitted around the user's head have not been taken well because the head attachment points 15 at the top of the mask as shown in figure 2, wrap around the cushion. Moreover, Amarasinghe on page 9, first paragraph, disclose that it will be appreciated that a user can make some adjustment to the position of the headgear retaining portion or the mask stabilizing feature or both so as to meet particular needs. This opportunity to make such adjustments allows for rapid tailoring of the mask assembly to a user's particular requirements." Thus, Amarasinghe does disclose brace head strap attachment points 15 (at least at the top of the mask as shown in figure 2) that wrap around the cushion when the straps are fitted around the user's head.

Regarding claim 23, and applicant's argument on page 15, last paragraph, that the brace 12 of Amarasinghe et al. does not correspond to the at least one selected frame portion because the brace of Amarasinghe does not engage the cushion, as recited in base claim 19 has not been taken well. Claim 19 does not require direct engagement and/or contact of the at least one selected frame portion with the cushion. Claim 19 merely recites that "at least one selected frame portion is engaged with the cushion." As discussed above, the selected frame portion (brace) 12 of Amarasinghe is engaged with the cushion (16) via the main body (13) and by wrapping around the cushion as seen in figure 2. Moreover, Amarasinghe discloses on page 8, lines 8-16 that "It is also intended that the brace could be configured so as to engage brace receiving features that may be provided by a mask cushion clip. In this way the brace may be accurately positioned relative to the mask frame while serving to secure the cushion clip and cushion to the mask frame." Thus, it is clear that Amarasinghe discloses at least one selected frame portion (12) engaged with the cushion (16) via the main body or a cushion clip.

Regarding claim 24, applicant argues on page 16, third full paragraph to page 17, end of first paragraph the examiner is simply incorrect in determining that a camming mechanism is not part of the mask assembly of claim 24 and that the examiner has speculated that the mask would be movable by a camming mechanism. The examiner respectfully disagrees. Claim 24 reads "The mask assembly of claim 19, wherein the main body and the at least one selected frame portion are moveable by a camming mechanism." Claim 24 is drawn to an apparatus, the apparatus is not claimed as having a cam, or a camming mechanism, as claim 24 only requires the main body and the at least one selected frame portion being capable of being moved by a camming mechanism. As discussed in the previous Office Action, since a cam is merely a projecting part of a rotating wheel or shaft that strikes a lever at one or more points on its circular path, if a cam were to contact the mask, or a package containing the mask, the main body and the selected portion would be movable by a camming mechanism.

Regarding claim 27, applicant argues, on page 17, fourth full paragraph, that Amarasinghe does not disclose at least one selected frame portion including each lateral side of a frame being made of a flexible material. However, the examiner respectfully disagrees. Amarasinghe discloses a malleable wire (constructed of 2.5mm gauge mild steel wire) as forming the brace (12). Mild steel has a relatively low tensile strength and is malleable and therefore meets the limitation of "being made from a flexible material" as the low tensile strength malleable steel is capable of being flexed (i.e. able to bend without breaking).

Regarding claim 34, applicant argues, on page 18, first paragraph to the end of the third paragraph that Amarasinghe does not disclose or suggest that the brace engages the cushion or that the brace 12 is bendable to cause lateral sides of the shell 13 to push against sides of the cushion 16. However, the examiner respectfully disagrees. As discussed above, Amarasinghe discloses a brace engaged with a cushion and the claim 34 does not required direct engagement and/or direct contact of the frame selected portion with the cushion. Claim 34 required the selected frame portion (brace 12 of Amarasinghe) includes each lateral side of the frame (portions 15 are formed of a malleable wire), and the selected frame portion (12) is bendable (capable of being bent) to cause each lateral side of the frame to push against sides of the cushion. Claim 34 does not require the lateral sides be bent, only that they a capable of being bent (i.e. bendable) and Amarasinghe clearly teaches side projecting members (15) that are capable of being bent to cause each lateral side of the frame to push against sides of the cushion. See: figures 2-4.

In response to applicant's arguments regarding claims 35 & 36, on page 18, last two paragraphs, that Amarasinghe does not disclose or suggest anything about the stabilizing portion 20 of the brace supporting the cushion 16, the examiner respectfully disagrees. Portion 20 is described by Amarasinghe as a the forehead stabilizing portion that is in near contact or contact with the user's forehead thereby limiting movement of the accompanying mask frame and mask cushion towards to the user's face in the region of the nasal bridge. Thus, portion 20 is a flexible member (i.e. it is a malleable wire) and it is supporting the cushion by limiting the cushions movement.

Applicant's arguments regarding claim 37, on page 19, first paragraph, have not been found convincing because the shell 13 and the brace 12 of Amarasinghe are two separate parts that are coupled together.

Regarding applicant's arguments to the rejection of claim 38, on page 19, second paragraph, have not been found convincing because the brace 12, which includes the lateral portions 15 is formed of a malleable wire (constructed of 2.5mm gauge mild steel) which is a flexible material (i.e. able to bend without breaking).

Regarding applicant's arguments to the rejection of claim 40, on page 19, third paragraph, have not been found convincing because the brace 12, which includes the lateral portions 15 is formed of a malleable wire (constructed of 2.5mm gauge mild steel) which is a flexible material (i.e. able to bend without breaking) and they are moveable (capable of being moved) relative to the main body to adjust the sides of the cushion.

Regarding applicant's arguments to the rejection of claim 21 under 35 U.S.C. § 103(a) over Amarasinghe et al. in view of Gradon et al. (U.S. Patent Application Publication 2003/0089373 A1) and claims 25, 26 and 28 which were rejected under 35 U.S.C. § 103(a) over Amarasinghe et al. in view of Hellings et al. (U.S. Patent 5,975,079) have been fully considered but have not been found convincing. Applicant essentially argues that Gradon and Hellings fail to cure the deficiencies of Amarasinghe and the combination of the references would not result in the claimed inventions. However, the examiner respectfully disagrees, for the reasons set forth above and those found in the Final Office Action mailed November 24, 2008.